Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Distraction Technique on Pain of Venipuncture in 3-6 Year-old Children

Protocol summary

Summary

Abstruct: The present study will be designed and conducted to determine the effect of video game play on pain of venipuncture in 3-6 year-old children.This randomized controlled trial study will be conducted on 80 hospitalized children with pain of venipuncture procedures. Playing a video computer game for children during the venipuncture procedures was the intervention for the interventional group. Also the intensity of pain was measured by behavioral pain scale for children (FLCC scale) during the procedure. This scale will be completed for patients without any intervention in the control group during venipuncture procedures. it seems that video game play intervention has a significant positive effect on the pain of venipuncture procedures in children. Further studies are recommended for the development of this technique in health care centers. Key Words: Distraction, Pain, venipuncture procedure, Children.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016032625029N3**
Registration date: **2016-05-05, 1395/02/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name

Sima Kaheni

Name of organization / entity

Faculty of nursing and medvifry, Mazandaran University of Medical Sciences, Sari, Iran

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

s.kaheni@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Mazandaran University of Medical Sciences

Expected recruitment start date

2016-03-29, 1395/01/10

Expected recruitment end date

2016-04-29, 1395/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Distraction Technique on Pain of Venipuncture in 3-6 Year-old Children

Public title

The Effect of Distraction Technique on Pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: were the age of child 3-6; alertness to place; time and person; having the ability to communicate; not having verbal and auditory disorders; the presence of a parent with the child. excluded criteria:event of a life-threatening emergency

Age

From **2 years** old to **5 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mazandaran University of Medical Sciences
Street address
Moalem Square
City
Sari
Postal code
4816715793
Approval date
2016-02-21, 1394/12/02
Ethics committee reference number
IR.MAZUMS.REC.94-1806

Health conditions studied

1

Description of health condition studied
Pain of Venipuncture
ICD-10 code
Z40,Z41,Z4
ICD-10 code description
Persons encountering health services for specific procedures and health care

Primary outcomes

1

Description
Pain
Timepoint
Before and during the intervention
Method of measurement
Flacc Scale

Secondary outcomes

empty

Intervention groups

1

Description
For the interventional group, 3 minutes before the venipuncture procedures, distraction started by displaying a game on a portable monitor and continued until the end of venipuncture procedures
Category
Other

2

Description
in the control group, venipuncture procedures was done without any intervention.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu-Ali Hospital
Full name of responsible person
Śima Kaheni
Street address
Imam square
City
Śari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
Street address
Moalem square
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Sima Kaheni

Position

Master degree/Facultymember

Other areas of specialty/work

Street address

School of Nursing and Midwifery Nusseibeh

City

Sari

Postal code

Phone

+98 11 3336 7342

Fax

Email

S.kaheni@mazums.ac.irkaheni20122yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Masou Bagheri nesami

Position

Phd/Faculty member

Other areas of specialty/work

Street address

School of Nursing and Midwifery Nusseibeh

City

Sari

Postal code

Phone

+98 11 3336 7342

Fax

Email

mbagheri@mazums.ac.iranna3043@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Sima Kaheni

Position

Master degree/Faculty member

Other areas of specialty/work

Street address

Nusibeh Nursing and Midwifey faculty

City

Sari

Postal code

Phone

+98 11 3336 7342

Fax

Email

S.kaheni@mazums.ac.irkaheni2012@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty